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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Lawrence M. Kauvar

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EXAMINER

VENCI, DAVID J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/714,163	KAUVAR, LAWRENCE M.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on December 20, 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-13 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-13 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges Applicant's Response filed December 20, 2004, which amended claims 7-12 and 20, and added new claims 21-22.

Currently, claims 7-13 and 20-22 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 7-13 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, lines 11 and 19, the recitation of "each intracellular localization pattern" is indefinite because it appears that only one intracellular localization pattern is recited in line 3. It is not clear whether/how "each intracellular localization pattern" is the same/or different from the first localization pattern recited in line 3.

In claim 7, the recitation of "optionally as a function of time" is indefinite because it is not clear whether the step of "recording" is a required claim limitation.

In claim 20, the recitation of "arbitrarily" in line 4 is indefinite because a person of skill in the art would not know how to ascertain the standard or degree of arbitrariness required by "arbitrarily." The term "arbitrarily" is a relative term that renders the claim indefinite because it is not defined by the claim, the

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specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 20, the recitation of "significant" in line 3 is indefinite because a person of skill in the art would not know how to ascertain the standard or degree of significance required by "significant." The term "significant" is a relative term that renders the claim indefinite because it is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 20, the step of "contacting" beginning on line 6 is indefinite because it is not clear whether this step is performed intracellularly.

In claim 20, the recitation of "each member" with respect to "each member of said first set of signal transduction proteins" or "each member of said second set of signal transduction proteins" lacks antecedent basis and is indefinite because the organizational structure of a "member" is not clear. For example, it is not clear whether "each member" corresponds to individual "signal transduction proteins" or whether "each member" corresponds to groups/subsets of "signal transduction proteins."

In claim 20, the recitation of "adding new signal transduction proteins" is indefinite because the identity of the other object(s) that the "new signal transduction proteins" are being added or combined with is not clear.

In claim 20, the recitation of "repeating the steps for which the second set of signal transduction proteins was used" is indefinite because it is not clear why it is necessary to repeat the same steps a second time. It is not clear whether/how the result of performing the same steps a second time would differ from the result obtained after the first performance.

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In claim 20, the recitation of "the range" lacks antecedent basis. Also, it is unclear what elements or characteristics comprise a "range."

In claim 20, the recitation of "marketed" is indefinite because it is unclear how markets or marketing is incorporated into Applicant's invention.

In claim 20, the recitation of "discarding those signal transduction proteins" is indefinite because it is not clear whether the "protein" is discarded from the method, or whether the "signal" is discarded from the method, or whether both the "protein" and the "signal" are discarded from the method.

***Claim Rejections - 35 USC § 102***

Claims 7, 9-10, 12-13 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Dunlay & Taylor (US 5,989,835).

Dunlay & Taylor teach a method to obtain a database (see Fig. 4, "data base 44") of signal transduction protein (see col. 9, line 36, "transcription factor") localization profiles (see Abstract, "distribution, environment") in response to toxic compounds (see Abstract, "compounds"), which method comprises: recording the intracellular localization pattern (see Abstract, "distribution, environment") of at least one signal transduction protein (see col. 9, line 36, "transcription factor") in a cell (see Abstract, "cell"), providing a set of toxic compounds (see Abstract, "compounds"), contacting each compound of said set of toxic compounds with said cell (see Abstract, "screening large numbers of compounds"), recording (see Abstract, "storing the data") the intracellular localization pattern (see Abstract, "distribution, environment") of at least one of said signal transduction proteins (see col. 9, line 36, "transcription factor") in said cell (see Abstract, "cell") as a function of time (see col. 6, line 22, "exposure time", col. 8, lines 8-9, "at each of the focal steps, an image is acquired"), wherein each intracellular localization pattern (see Abstract,

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"distribution, environment") is constructed by concurrently determining the presence, absence or amount (see Abstract, "distribution, environment, or activity") in at least three cellular locations (see col. 11, lines 23-46), wherein each intracellular localization pattern is recorded in computer-readable and retrievable form (see Abstract, "storing the data").

With respect to claims 9-10, Dunlay & Taylor teach a method wherein the intracellular localization patterns of a multiplicity of signal transduction proteins are determined (see col. 11, lines 23-46).

With respect to claim 12, Dunlay & Taylor teach a method wherein labeling antibodies are used (see col. 4, lines 2-3).

With respect to claim 22, Dunlay & Taylor teach a method comprising multiple cell types (see col. 5, line 36, "cell selection settings", col. 9, line 64, "chondrocyte", col. 10, line 57, "myocytes", col. 11, line 13, "normal and hypertrophic cells").

### ***Claim Rejections - 35 USC § 103***

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunlay & Taylor (US 5,989,835) in view of Mochly-Rosen, 268 SCIENCE 247 (1995).

Dunlay & Taylor describe a method to obtain a database of signal transduction protein localization profiles as substantially described *supra*. Dunlay & Taylor do not teach a method incorporating protein kinase C (PKC).

However, Mochly-Rosen teaches a method incorporating PKC (See *e.g.* Fig. 2) in order to observe the effect of various toxic compounds on PKC translocation. Therefore, it would have been obvious for a

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person of ordinary skill in the art to use the method of Dunlay & Taylor with PKC because Mochly-Rosen teaches that the localization of serine-threonine kinases, including PKC, through protein-protein interactions is an essential component of signal transduction and provides an important means of regulation (see p. 250, col. 3). Furthermore, Mochly-Rosen teaches that the localization of serine-threonine kinases may be useful in the development of therapeutic agents (see ABSTRACT).

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Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunlay & Taylor (US 5,989,835) in view of Gerhard (US 5,684,628).

Dunlay & Taylor describe a method to obtain a database of signal transduction protein localization profiles as substantially described *supra*. Dunlay & Taylor do not teach the use of a wide-field microscope.

However, Gerhard teaches a wide-field microscope for illuminating biologically active samples (see col. 3, lines 29-31). Therefore, it would have been obvious for a person of ordinary skill in the art to use the method of Dunlay & Taylor with a wide-field microscope because Gerhard teaches that a wide-field microscope, along with conventional digital imaging and signal processing techniques, can be used to provide a three dimensional, time domain and optical frequency domain image of a biologically active specimen. Gerhard also teaches that such images are particularly valuable in the field of fluorescence microscopy where images of the specimen are not only integrated over time, but wavelength as well (see col. 1, lines 31-34).

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Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunlay & Taylor (US 5,989,835) in view of Cook (US 6,546,378).

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Dunlay & Taylor describe a method to obtain a database of signal transduction protein localization profiles as described *supra*. In addition, Dunlay & Taylor teach a method for screening signal transduction protein targets (see Title, "cell-based screening", col. 1, lines 9-19, "disease targets", col. 10, lines 17-18, "other transcription factors", col. 11, lines 13-21, "a particular cellular protein") against added compounds.

Dunlay & Taylor do not teach a method incorporating "principal components."

However, Cook teaches a method incorporating principal component analysis (see col. 19, lines 33-34) in order to process data from pharmaceutical drug-effect studies (see col. 3, lines 25-26) and test and evaluate drugs (see col. 19, line 30). Therefore, it would have been obvious for a person of ordinary skill in the art to perform the method of obtaining a database of signal transduction protein localization profiles, as described by Dunlay & Taylor, with principal component analysis because Cook discovered a method that can "uncover, capture, and discover the presence of complex patterns that are distributed across many channels, frequencies, times, and/or other features simultaneously" (see col. 6, lines 4-7).

### ***Response to Arguments***

In prior Office Action, claim 7 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for lack of correspondence between the claim preamble and the method outcome. In addition, claims 7-13 were rejected under 35 U.S.C. 112, first paragraph, for failing to enable "a method to obtain a database." In response, Applicant provides thorough argumentation to persuasively traverse these rejections. Accordingly, these rejections are withdrawn (see Search Notes, submitted herewith).

In prior Office Action, claim 7 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "optionally as a function of time." In response, Applicant amended claim 7 to remove the term "observing." In addition, Applicant argues that the term "recording" may be performed continuously



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or instantaneously. Although Applicant's arguments are generally persuasive, nevertheless, the recitation of "optionally as a function of time" remains indefinite because it is not clear whether the step of "recording" is a required claim limitation.

In prior Office Action, claim 20 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "arbitrarily." In response, Applicant argues that the term arbitrarily "conveys to one of ordinary skill the fact that the selection process is not critical to the claimed invention and can be accomplished randomly or in any manner consistent with the interests or needs of the practitioner of the method" (see Applicant's Remarks at p. 9, second paragraph). Applicant's argument has been carefully considered but is not persuasive because, although the step may not be critical to the claimed invention, nevertheless, the scope of the claim is rendered indefinite by the usage of the term "arbitrarily." In addition, Applicant's specification does not appear to define a method of ascertaining the "interests" or "needs" of practitioners of the method.

In prior Office Action, claim 20 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "principle [sic] components." In response, Applicant has informed Examiner of an art-recognized definition of "principal components." Accordingly, this rejection is withdrawn.

In prior Office Action, claim 20 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "the range." In response, Applicant argues that the term "the range" is analogous to the term "the group" commonly used to introduce a Markush group, and therefore requires no antecedent basis. Applicant's argument has been carefully considered but is not persuasive because Applicant's analogy is improper. The term "the group" used in the context of introducing a Markush group does not require antecedent basis because it is an art-recognized syntax for introducing a Markush group. In contrast, the term "the range" is not an art-recognized syntax for introducing "compounds" as recited in claim 20, and therefore requires antecedent basis.

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In prior Office Action, claim 20 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "marketed." In response, Applicant argues that the term "marketed" is clear if the term is read in the context in which "market" is used (i.e. "the range of compounds marketed as small organic molecules"). Applicant's argument has been carefully considered but is not persuasive. Even if the term "marketed" is read in the context in which "market" is used, nevertheless, the term "marketed" remains indefinite because the context itself, i.e. "the range of compounds marketed as small organic molecules," is indefinite. It is not clear whether/how markets or marketing is related to "a method to identify a set of signal transduction proteins" or whether a marketing step is a required claim limitation.

In prior Office Action, claims 7-13 and 20 were rejected under 35 U.S.C. 102(b) or 35 U.S.C. 103(a) in view of Gerdes & Kaether, 389 FEBS LETTERS 44 (1996), or Sawin & Nurse, 94 PROC. NATL. ACAD. SCI. USA 15146 (1996). In light of Applicant's amendment to the claims, and in light of new art rejections in view of Dunlay & Taylor (US 5,989,835), set forth supra, all claim rejections based on Gerdes & Kaether and Sawin & Nurse are withdrawn. Discussion pertaining to Gerdes & Kaether and Sawin & Nurse is rendered moot.

### ***Conclusion***

No claims are allowable at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

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64/26/05